

REMARKS

Claims 1, 5-15 and 17-19 were pending and have been examined on the merits. Claims 7, 11-12, 15 and 18 are amended hereinabove, claim 17 is cancelled and claims 20-21 are added. Support for amended claim 15 can be found in the subject matter of claim 17 and support for new claims 20 and 21 can be found in the subject matter of claims 7 and 11. No new matter has been added.

In the Office Action, the claims are rejected as follows:

1. Claims 15 and 17-19 are rejected under 37 C.F.R. § 112, ¶ 1, because the specification is allegedly non enabling for the treatment of any and all types of diseases;
2. Claims 7, 11-13 and 15-19 are rejected to under 37 C.F.R. § 112, ¶ 2 for allegedly being indefinite;
3. Claims 1 and 5-11, 14-15, 17 and 19 are rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Bromberg et al. (U.S. Patent Application Publication No. 20030152623, hereinafter “Bromberg”) in view of Blum et al. (U.S. Patent No. 6,294,591, hereinafter “Blum”) and Giammona et al. (Biochimica et Biophysica Acta, 1999, hereinafter “Giammona”); and
4. Claims 1, 8, 11-13, 15 and 17-18 are rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Bromberg in view of Blum, Giammona and Cavazza (U.S. Patent No. 6,013,670, hereinafter “Cavazza”).

Applicants respectfully traverse.

Rejection under 37 C.F.R. § 112, ¶ 1

Claim 17 is cancelled hereinabove and claim 15 is amended to incorporate its subject

matter. Thus, it is respectfully submitted that the specification is enabling for the claimed subject matter and withdrawal of the rejection under 37 C.F.R. § 112, ¶ 1, is respectfully submitted.

Rejection under 37 C.F.R. § 112, ¶ 2

Claims 7 and 11-12 are amended hereinabove. Accordingly, Applicants respectfully request that in light of the claim amendment the rejection under 37 C.F.R. § 112, ¶ 2 be reconsidered and withdrawn.

Rejections under 37 C.F.R. § 103(a)

a) Claims 1, 5-11, 14-15, 17 and 19

Applicants wish to incorporate herein by reference the previous responses and wish to add the following additional remarks.

As previously submitted, the presently claimed invention is directed to anionic hydrogel matrixes obtained by means of irradiation of polymers suitably derivatised with photoreticulable groups, wherein the photoreticulable groups are derived from the insertion of glycidyl methacrylate (GMA) and methacrylic anhydride (MA) in the side chain of PHEA in the presence of acid comonomers (*e.g.*, 4, lines 11-23, page 9, lines 10-19 and from page 13, line 12 to page 15 line 24).

As also previously submitted Bromberg does not disclose Applicants' invention. Bromberg only provides for a plethora of suitable polymers which do not include the polyaspartamide derivatized polymers presently claimed (*e.g.*, paragraphs [0087]-[0115] for a total of 11 pages).

Thus, one skilled in the art would find no motivation to choose a poly-L-aspartic acid among the laundry list of components disclosed in Bromberg to modify it as presently claimed

with a reasonable expectation of success. *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007) (“A claimed compound would not have been obvious where it was not obvious to try to obtain it from a broad range of compounds, any one of which could have been selected as the lead compound for further investigation,and there was not reasonable expectation of success”).

Moreover, knowledge of applicant’s disclosure must be put aside in reaching the determination of whether the claimed invention “as a whole” would have been obvious to a person of ordinary skill in the art when the invention was unknown and just before it was made. In other words, impermissible hindsight must be avoided and the legal conclusion of obviousness must be reached on the basis of the facts gleaned from the prior art.

Thus, Applicants respectfully submit that it would be impossible for a person of ordinary skill to select the poly-L-aspartic acid among 11 pages of disclosure of Bromberg without the help of impermissible hindsight with a reasonable expectation of success to be capable to modify it as presently claimed.

As also previously submitted, Blum does not correct Bromberg’s deficiencies because it suffers from the same defects. Namely, Blum describes that it is possible to form polymers with reactive side groups but it is completely silent with regard of PHEA (e.g., col. 1, line 63 to col. 2 line 3). Further, Applicants submit that Blum is not analogous to the field of Applicants’ endeavor (MPEP § 2141.01(a)) and therefore it should not be used as a reference for sustaining a *prima facie* obviousness rejection against Applicants’ claims. *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2008). The court in *Agrizap* held that analogous art is not limited to references in the field of endeavor of the invention, but it also includes references that would have been recognized by those of ordinary skill in the art as useful for Applicants’

purpose.

However, the facts of the present case are quite different. Unlike in *Agrizap* and as submitted before, Blum relates only to polymers known and used to produce radiation-curable coatings, paints, adhesives or impregnating compositions (e.g., col. 1, lines 9-11). These are not the purposes of the presently claimed invention. To the contrary, these purposes are completely irrelevant and useless for Applicants' invention which relates to the field of pharmaceutical technology. Thus, Applicants respectfully points out that Blum should not be considered as a suitable 35 U.S.C. § 103(a) reference against Applicants' claimed subject matter.

Finally, Applicants has also previously submitted that Giammona only provides for the synthesis and characterization of new biodegradable biogels (e.g., the abstract). However, as also previously submitted, Giammona is completely silent with regard to PHEA derivatisable with GMA and MA and to the presence of acid comonomers.

Thus, for the following reasons, Applicants assert that the combination of the cited references would not have rendered obvious the presently claimed subject matter to one skilled in the art.

First, obviousness can be established only by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so. *In re Kahn*, 441, F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006). As discussed above, Bromberg provides no motivation to select poly-L-aspartic acid and to modify it as described by Blum, because Blum cannot be used to sustain a *prima facie* obviousness rejection against Applicants' claims. Thus, it cannot provide a motivation to insert MA and PHEA photo-cross linked by insertion of GMA into the side chains, because it cannot provide any useful teachings for the person of skills in the pharmaceutical art.

Moreover, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ____, 82 USPQ2d 1385, 1396 (2007). The simple reason that Bromberg, Blum and Giammona can be combined is not enough to render obvious the claimed subject matter because one of ordinary skill in the art would not even have considered Blum as a reference for rendering obvious the presently claimed subject matter. Thus, unlike stated by the Examiner on pages 15 and 21 of the Office Action, the person of ordinary skill would not have had any reasonable expectation of success in producing the claimed invention starting from the teachings of the combination of the cited references.

Thus, for all of the reasons set forth above, Applicants respectfully request that the rejection of claims 1, 5-11, 14-15, 17 and 19 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

b) Claims 1, 8, 11-13, 15 and 17-18

As set forth above, the combination of Bromberg with Blum and Giammona fails to render obvious the presently claimed subject matter to one of ordinary skill in the art.

However, Cavazza does not make up for their deficiencies. As an initial matter, the teachings of Cavazza are irrelevant with regard to the presently claimed anionic hydrogel matrix composition as recited in claim 1, the only independent claim. Cavazza only provides for the treatment of chronic inflammatory bowel diseases with lower alkanoyl L-carnitines (e.g., col. 1, lines 6-10). Thus, it cannot contribute to render obvious the subject matter of claim 1, nor the subject matter of any of the claims depending from it.

Accordingly, Applicants respectfully request that the rejection of claims 1, 8, 11-13, 15 and 17-18 under 35 U.S.C. § 103(a) for allegedly being obvious over the combination of the

cited references be reconsidered and withdrawn.

Conclusions

This response is being filed within the shortened statutory period for response. Thus, no further fees are believed to be required. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275.

Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,
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Dated: June 30, 2011

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